UNITED STATES FOOD & DRUG ADMINISTRATION

Record Retention Requirements for the Soy Protein/CHD Health Claim

OMB Control No. 0910-0428

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. Section 403(r)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(3)(A)(i)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health-related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Section 101.82 (21 CFR 101.82) of our regulations authorizes a health claim for food labels about soy protein and the risk of coronary heart disease (CHD). Accordingly, we established this ICR in support of the regulation. While we are currently proposing to revoke the regulation (RIN 0910-AH43) as announced in the *Federal Register* of October 31, 2017 (82 FR 50324), the regulation remains in effect.

We therefore request extension of OMB approval for the information collection provisions found in 21 CFR 101.82: *Health claims: Soy protein and risk of coronary heart disease (CHD).*

2. Purpose and Use of the Information Collection

The information collection enables us to review food labeling to determine the basis of soy protein/CHD health claims. Respondents are required to retain records for FDA inspection regarding calculation of the ratio of soy protein to other sources of protein in a food when that food bears a soy protein/CHD health claim.

Description of Respondents: Respondents include businesses engaged in the manufacture of foods containing soy and other proteins that bear soy protein/CHD health claims. Respondents to the information collection are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

The regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for use by firms. Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials. We estimate ninety-five percent (95%) of the recordkeeping will be maintained electronically.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We estimate ten percent (10%) of recordkeepers are small businesses, however we do not believe the information collection imposes undue burden on small entities. We aid small businesses in dealing with the requirements of the FD&C Act through the agency's Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide assistance via FDA's Small Business Assistance webpage on the agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

Data collection occurs occasionally. There are no consequences to Federal programs or policy activities if the information is not collected or is collected less frequently.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances associated with this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of October 21, 2020 (85 FR 66999). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

Company records such as nutrient databases or analyses, recipes or formulations, and purchase orders for ingredients, which may be consulted or copied during FDA inspections, often contain trade secret and confidential commercial information. This information is safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20 of our regulations (21 CFR part 20).

Privacy Act

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports Record Retention Requirements for Soy Protein/CHD Health Claim. All records are maintained at the facility.

Record Retention Requirements for Soy Protein /CHD provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health-related condition only where that statement meets the requirements of the regulations promulgated by the Secretary of Health and Human Services to authorize the use of such a health claim. Regulations authorize a health claim for food labels about soy protein and the risk of coronary heart disease. The information collection enables FDA to review food labeling to determine the basis of soy protein/CHD health claims and respondents

are required to retain records for FDA inspection regarding calculation of the ratio of soy protein to other sources of protein in a food when that food bears a soy protein/CHD health claim.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not maintain information collected by facilities and does not use name or any other personal identifier to retrieve records from the information collected.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions and does not involve any questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden[1]

21 CFR 101.82	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeping	Total Hours
Health claims: Soy protein and risk of coronary heart disease (CHD)	25	1	25	1	25

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon our experience with the use of health claims, we estimate 25 firms market products bearing a soy protein/CHD health claim and that, perhaps, one of each firm's products might contain non-soy sources of protein along with soy protein. The records required to be retained by § 101.82(c)(2)(ii)(B) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer is limited to assembling and retaining the records, which we estimate will take 1 hour annually.

12b. Annualized Cost Burden Estimate

We estimate the annualized cost burden for assembling and retaining the required records is $2,484.00. This estimate assumes a recordkeeper’s average wage to be that of a Federal government employee at the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2021, which makes the annual wage cost for assembling and retaining the required records approximately $1,242.00 (25 hours x $49.68 per hour). To account for overhead, this cost is increased by 100%, making the total estimated burden hour cost to the recordkeepers $2,484.00.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

FDA review of the retained records occurs as part of scheduled firm inspections. Assuming it takes one hour per product record review (25 products x one hour = 25 hours), we estimate the annual cost to the Federal government is 25 hours at the rate of $49.68/hour (the GS-13/Step-1 rate for the Washington-Baltimore locality pay area for the year 2021) (25 hours x $49.68/hour = $1,242.00). To account for overhead, we multiplied this cost by 100%, making the total estimated annual cost to the Federal government $2,484.00.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

The information obtained from this information collection will not be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.